Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Intravenous Fluid Therapy before Colonoscopy on Arterial Blood Oxygen Saturation, Heart Rate and Patients' Blood Pressure

Protocol summary

Study aim
The aim of this study was to the effect of intravenous fluid therapy before colonoscopy on arterial blood oxygen saturation, heart rate and blood pressure of patients.

Design
This study was a randomized clinical trial with two groups (intervention and control), pre and post-test design, and not-blinded.

Settings and conduct
This study was conducted on 60 patients who referred to Ghaem hospital of Mashhad that were randomly divided into two groups (n = 30).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Lower gastrointestinal disorders.
Exclusion criteria: Severe bleeding during the study.

Intervention groups
Intervention group: in intervention group, patients were received one liter of 1/3-2/3, one hour before colonoscopy. Control group: in control group, was conducted routine colonoscopy.

Main outcome variables
Arterial Blood Oxygen Saturation; Heart Rate; Blood Pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181010041302N1**
Registration date: **2018-11-02, 1397/08/11**
Registration timing: **retrospective**

Last update: **2018-11-02, 1397/08/11**
Update count: **0**

Registration date
2018-11-02, 1397/08/11

Registrant information

Name
Mohammad Rajabpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-06-30, 1395/04/10

Expected recruitment end date
2016-10-31, 1395/08/10

Actual recruitment start date
2016-06-30, 1395/04/10

Actual recruitment end date
2016-10-31, 1395/08/10

Trial completion date
2016-12-30, 1395/10/10

Scientific title
The Effect of Intravenous Fluid Therapy before Colonoscopy on Arterial Blood Oxygen Saturation, Heart Rate and Patients' Blood Pressure

Public title
The Effect of Intravenous Fluid Therapy on Blood Circulation Indexes of Patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Lower gastrointestinal disorders

Exclusion criteria:
Severe bleeding during the study

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients divided to intervention and control group with simple randomization method (with lottery of sampling days).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The patients divided to intervention and control group with simple randomization method (with lottery of sampling days).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building, University St

City

Mashhad

Province

Razavi Khorasan

Postal code

9781414878

Approval date

2015-12-25, 1394/10/04

Ethics committee reference number

IR.MUMS.REC.94.261

Health conditions studied

1

Description of health condition studied

Arterial Blood Oxygen Saturation

ICD-10 code

-

ICD-10 code description

-

2

Description of health condition studied

Heart Rate

ICD-10 code

-

ICD-10 code description

-

3

Description of health condition studied

Blood Pressure

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Arterial Blood Oxygen

Timepoint

Before the intervention and the 1, 3, 5, 9 and 10 minute after colonoscopy

Method of measurement

Researcher-made Checklist for the Control of Cardiovascular Status

2

Description

Heart Rate

Timepoint

Before the intervention and the 1, 3, 5, 9 and 10 minute after colonoscopy

Method of measurement

Researcher-made Checklist for the Control of Cardiovascular Status

3

Description

Blood Pressure

Timepoint

Before the intervention and the 1, 3, 5, 9 and 10 minute after colonoscopy

Method of measurement

Researcher-made Checklist for the Control of Cardiovascular Status

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in intervention group, patients were received one liter of 1/3-2/3, one hour before colonoscopy.
Category
Prevention

2

Description
Control group: in control group, was conducted routine colonoscopy.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Mostafa Dastani
Street address
Endoscopy Department, GHaem Hospital, Ahmad Abad St, Dr Shariati Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Rajabpoor
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
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Mashhad Faculty of Nursing and Midwifery, Ebn-e Sina St, Doktora Crossroads
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The study report published in the dissertation form and article for researcher.
When the data will become available and for how long
The start of access is 6 months after the announcement of the results.
To whom data/document is available
Researchers at university centers
Under which criteria data/document could be used
Data is authorized only with permission from the author of the articles and with the source.
From where data/document is obtainable
Mohammad Rajabpoor, Paramedical School, Contact Number: 00989158341840, Email: Rajabpoor.m@bums.ac.ir
What processes are involved for a request to access data/document
After submitting a request, the request is reviewed and, if the request is accepted, is answered within 1 month.
Comments